FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	ATTY. DOCKET NO. P32875-1	SERIAL NO. 10/055,817
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use several sheets if necessary)*	APPLICANT Buxton et al.	
	FILING DATE Jan. 23, 2002	GROUP 1614 / 1615

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	AA	US 5,852,014	Dec 22, 1998	Gaster et al.			
	AB	US 5,998,409	Dec 7, 1999	Gaster et al.			
		US pending patent application 10/344075, US national phase of PCT/GB01/03544	PCT/GB01/ 03544 filed on August 7, 2001	Bonhomme, Bril, Gout, Patel, et al.			

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes / No
	BA	WO 02/11766 A2 =PCT/GB01/03544	PCT filing date August 7, 2001 PCT publication date Feb 14th, 2002.	PCT			
	BB	EP 0 884 319 A2	Dec 16, 1998	EPO			
	BC	WO 93/18036 A1	Sept 16, 1993	PCT			
	BD	WO 98/07728 A1	Feb 26, 1998	PCT			
	BE	EP 0 104 053 A1	March 28, 1984	EPO			
	BF	WO 03/068193 A1	Aug 21, 2003	PCT			
	BG	WO 96/22082 A1	July 25, 1996	PCT			
	BH	WO 98/11067 A1	March 19, 1998	PCT			
	BI	WO 00/03983 A1	Jan 27, 2000	PCT			
	BJ	WO 00/03984 A1	Jan 27, 2000	PCT			
	BK	WO 99/29697 A1	June 17, 1999	PCT			
	BL	WO 00/17207 A1	March 30, 2000	PCT			
	BM	WO 95/28927 A1	Nov. 2, 1995	PCT			

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	CA	"Remington's Pharmaceutical Sciences", 16th edition, 1980, editor A. Osol, Mack Publishing Company, Pennsylvania, Chapter 89: "Tablets, Capsules and Pills", pages 1553-1584.

	CB	"Remington's Pharmaceutical Sciences", 18th edition, 1990, Mack Publishing Company, Pennsylvania, pages 1641 to 1644: "Methods of preparation: Wet-Granulation Method" section.
	CC	"Remington's Pharmaceutical Sciences", 15th edition, 1975, managing editor J.E. Hoover, Mack Publishing Company, Pennsylvania, single page extract from "Methods of preparation: Wet-Granulation Method" section.
	CD	"Handbook of Pharmaceutical Granulation Technology", ed. D.M. Parikh, 1997, Marcel Dekker Inc., New York: Preface, contents, Introduction, Chapters 1-2 (pages 1-23), Chapter 4 (pages 59-73), and Chapter 7 (pages 151-204).
	CE	P.H. List et al., "Hagers Handbuch der Pharmazeutischen Praxis", 4th edition, 1971, vol. 7, Part A, Springer-Verlag, pages 312-313, part of section entitled "Granulate" (in German); and English translation thereof
	CF	"Handbook of Pharmaceutical Excipients", 3rd edition, 2000, ed. A.H. Kibbe, American Pharmaceutical Association, Washington, pages: 56-69, 299-302, 252-255, 433-439, 240-248, 195-200, 336-339, 102-106, 501-504, 160-164, 305-308, 70-72.
	CG	Extract from Confidential SmithKline Beecham Pharmaceuticals clinical trial protocol 207266/052: Appendix D thereto entitled "Specimen Written Informed Consent to participate in a clinical trial – Information for patients – 207266/052. Study title: A double-blind, placebo-controlled dose ranging study to copmpare the efficacy and safety of three doses of SB-207266-A (5mg, 1mg and 0.25mg od) with placebo over 24 weeks in the treatment of irritable bowel syndrome". The Written Informed Consent will probably have been disclosed to patients participating in the trial in 1998, and this disclosure may or may not have been made explicitly or implicitly in confidence. (1998).

	CH	Master Batch Record SB207266\AV-AA-03. Internal confidential SmithKline Beecham manufacturing process description for tablets containing SB207266. The tablets are thought to have been released in or around 1998 for human oral administration as part of one or more clinical trials, probably *inter alia* held in the US, and *inter alia* according to clinical trial protocol 207266/052 (document CG) stated above. The release of tablets may or may not have been made explicitly or implicitly in confidence. As shown in the document, the tablets are thought to have been formed by blending and tabletting a mixture of: (a) 90 mg of "platform granules", the 90mg containing SB-207266 hydrochloride (5.0 mg, presumably measured as free base) and other intragranular excipients, and (b) the following extragranular excipients: microcrystalline cellulose (Avicel PH102, 12.0 mg), mannitol (Pearlitol SD200, 45.0mg), and magnesium stearate (3.0 mg), for a total tablet weight of ca. 150 mg. Including the drug and both the intragranular and extragranular excipients, the total ingredients of the tablets are thought to be as follows: SB-207266 hydrochloride (5.0 mg, presumably measured as free base), microcrystalline cellulose (30.0 mg), mannitol (112.0mg), and magnesium Stearate (3.0 mg), for a total Tablet weight of ca. 150 mg.
	CI	L.M. Gaster et al., "N-[(1-butyl-4-piperidinyl)methyl]-3,4-dihydro-2H-[1,3]oxazino[3,2-a]indole-10-carboxamide hydrochloride, the first potent and selective 5-HT_4 receptor antagonist amide with oral activity", *J. Med. Chem.*, vol 38, pp. 4760-4763 (1995).
	CJ	L. Gaster, "SB-207266, $5HT_4$ receptor antagonist, agent for irritable bowel syndrome", *Drugs of the Future*, vol. 22(12), pp. 1325-1332, (1997)
	CK	L.A.Houghton et al. "$5HT_4$ receptor antagonism in irritable bowel syndrome: effect of SB-207266-A on rectal sensitivity and small bowel transit", *Aliment. Pharmacol. Ther.*, vol. 13, pp. 1437-1444 (1999).
	CL	L.A.Houghton et al. "$5HT_4$ antagonism in irritable bowel syndrome (IBS): Effect of SB-207266-A on rectal sensitivity and small bowel transit", *Gut*, vol. 41 (Suppl. 3), page A26 (abstract 17.09) (1997)
	CM	S.M.Cooper et al., "A pharmacodynamic model of 5-HT4 receptor activation in man: antagonism by the 5-HT4 receptor antagonist SB-207266", *Gastroenterology*, vol. 116(4), p. A598, abstract G2620 (1999).
	CN	A.E. Bharucha et al., "Effects of a serotonin 5-HT_4 receptor antagonist SB-207266 on gastrointestinal motor and sensory function in humans", *Gut*, vol. 47, pp. 667-674 (2000).
	CO	Confidential letter dated 30 August 2000 from Aoyama & Partners, Japan, attaching the English translation of a response letter submitted by Aoyama & Partners to Japanese Patent Office on August 8th, 2000 in respect of Japanese patent application 508219/1991, and probably publically available at the Japanese Patent Office on or soon after August 8th, 2000.

	CP	CONSENT FORM for SmithKline Beecham clinical trial SB 207266/091 entitled "A SINGLE AND REPEAT DOSE, DOSE-RISING STUDY TO EVALUATE THE SAFETY, TOLERABILITY AND PHARMACOKINETICS OF SB 207266 WHEN ADMINISTERED TO HEALTHY SUBJECTS". 12 Oct 2000 version consent form, approved by International Review Board (IRB) on Oct 16, 2000, signed by first volunteer on Oct 19, 2000 (confidential volunteer name blacked out). This disclosure may or may not have been made explicitly or implicitly in confidence.
	CQ	CONSENT FORM for SmithKline Beecham clinical trial SB 207266/091 entitled "A SINGLE AND REPEAT DOSE, DOSE-RISING STUDY TO EVALUATE THE SAFETY, TOLERABILITY AND PHARMACOKINETICS OF SB 207266 WHEN ADMINISTERED TO HEALTHY SUBJECTS". Jan 10, 2001 version consent form, approved by IRB on Jan 10, 2001, signed by first volunteer on Feb 12, 2001. This disclosure may or may not have been made explicitly or implicitly in confidence.
	CR	CONSENT FORM for SmithKline Beecham clinical trial SB 207266/091 entitled "A SINGLE AND REPEAT DOSE, DOSE-RISING STUDY TO EVALUATE THE SAFETY, TOLERABILITY AND PHARMACOKINETICS OF SB 207266 WHEN ADMINISTERED TO HEALTHY SUBJECTS". March 5, 2001 version consent form, approved by IRB on March 7, 2001, signed by first volunteer on March 15, 2001. This disclosure may or may not have been made explicitly or implicitly in confidence.
	CS	2 CONSENT FORMS for SmithKline Beecham clinical trial SB 207266/083 entitled "A Study to Evaluate the Effect of Steady-State SB 207266 on the Single-Dose Pharmacokinetics, Pharmacodynamics as well as Safety and Tolerability of Warfarin in Healthy Subjects". Jan 30, 2001 version consent form, approved by IRB on Feb 8, 2001, signed by first two volunteers on Feb 12, 2001. This disclosure may or may not have been made explicitly or implicitly in confidence.
	CT	Communication from European Patent Office (EPO) dated 21 October 2003, according to Article 96(2) EPC, alleging deficiencies in the corresponding European patent application 01 954 214.1 (derived from the current PCT application PCT/GB01/03590)
	CU	International Preliminary Examination Report (IPER) dated 3 Sept 2002 in respect of the current PCT application PCT/GB01/03590
	CV	Letter dated 19 August 2002 from Dr David Waters of GlaxoSmithKline to the European Patent Office responding to the PCT IPEA Written Opinion of 19 April 2002 in respect of the current PCT application PCT/GB01/03590
	CW	G.J. Sanger et al., "SB-207266: 5-HT_4 receptor antagonism in human isolated gut and prevention of 5HT-evoked sensitization of peristalsis and increased defaecation in animal models", *Neurogastroenterol. Mot.*, vol 10, pp. 271-279, (1998).

	CX	G.J. Sanger et al., "Increased defecation during stress or after 5-hydroxytryptophan: selective inhibition by the 5-HT_4 receptor antagonist SB-207266", *Br. J. Pharmacol.*, vol 130, pp. 706-712 (2000).
	CY	G.A. Kennett et al., "Anxiolytic-like actions of the selective 5-HT_4 receptor antagonists SB 204070A and SB 207266A in rats", *Neuropharmacology*, vol 36, no 4/5, pp. 707-712 (1997).
	CZ	K.A. Wardle et al., "Selective and functional 5-hydroxytryptamine$_4$ receptor antagonism by SB 207266", *Br. J. Pharmacol.*, vol 118, pp. 665-670, (1996).
	CZ1	M.I. Smith et al., "5-HT_4 receptor antagonism potentiates inhibition of intestinal allodynia by 5-HT_3 receptor antagonism in conscious rats", *Neuroscience Letters*, vol. 271, pp. 61-64, (1999).
	CZ2	M. Fedouloff et al., "Synthesis and pharmacological activity of metabolites of the 5-HT_4 receptor antagonist SB-207266", *Bioorg. Med. Chem.*, vol. 9, pp. 2119-2128, (2001).
	CZ3	F. de Ponti et al., "Irritable Bowel Syndrome: new agents targeting serotonin receptor subtypes", *Drugs*, vol. 61(3), pp. 317-332, (2001).
	CZ4	"Handbook of Pharmaceutical Excipients", 2nd edition, 1994, ed. A. Wade and P.J. Weller, American Pharmaceutical Association, Washington, pages: 52-62, 274-277, 229-232, 219-228, 186-190, 306-309, 392-399, 84-87, 462-466, 141-144, 280-282, 63-65.
	CZ5	"Pharmaceutical Powder Compaction Technology", editors G. Alderborn and C. Nyström, possibly Marcel Dekker publishers, published before August 2001, pages 283, 288-289, 298-299, 302-303.
	CZ6	"International Cosmetic Ingredient Dictionary and Handbook", 7th edition, volume 2, 1997, pp. 1617-1618 and p. 1625.

EXAMINER	DATE CONSIDERED 7/04

·EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copyof this form with next communication to applicant.

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DATE: April 18, 2000 SHEET _1_ of _2

Form PTO-1449 (Modified)

FORM PTO-1449 (Modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.	SERIAL NO.
	6446.US.P2	09/541,795
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT	
	J. Link, et al.	
(Use several sheets if necessary)	FILING DATE	GROUP
	03/31/00	(not yet assigned)
(37 CFR 1.98 (b))		

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
		5 8 1 7 8 6 2	10/06/98	Poetsch et al.	—	—	

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLIC-ATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANS-LATION YES	TRANS-LATION NO
		9 8 1 3 3 4 7	02.04.98	PCT	—	—		
		9 9 1 1 2 5 8	11.03.99	PCT	—	—		

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

		Springer, T.A., 1994, Traffic Signals for Lymphocyte Recirculation and Leukocyte Emigration: The Multistep Paradigm, CELL, 76: 301-314.
		Lawrence, M.B., Springer, T.A., 1991, Leukocytes' Roll on a Selectin in Physiologic Flow Rate: Distinction from and Prerequisite for Adhesion Through Integrins, CELL, 65:859-873.
		Von Adrian, V., Chambers, J.D., McEnvoy, L.M. Bargatze, R.F., Arfos, K.E., Butcher, E.C., 1991, Two-Step Model of Leukocyte-Endothelial Cell Interactions in Inflammation, Proc. National Acad. Sci. USA, 88:7538-7542.
		Ley, K., Gaehtgens, P., Fennie, C., Singer, M.S., Lasky, L.H., Rosen, S.D., 1991, Lectin-Like Cell Adhesion Molecule 1 Mediates Rolling in Mesenteric Venules, in vivo, BLOOD, 77:2553-2555.
		Higuchi, T., Stella, V., Pro-drugs as Novel Delivery Systems, Vol. 14 of the A.C.S. SYMPOSIUM SERIES.
		Roche, E.B., Bioreversible Carriers in Drug Design, AMERICAN PHARMACEUTICAL ASSOCIATION AND PERGAMON PRESS, 1987.
		Prescott, E., Methods in Cell Biology, Volume XIV, Academic Press, New York, NY (1976), p. 33 et seq.
		Berge, S.M., et al., J. PHARMACEUTICAL SCIENCES, 1977, 66:1 et seq.
		Kakimoto, et al., CELL IMMUNOL 142:326-337, 1992.
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DATE: April 18, 1999 SHEET _2_ of _2

Form PTO - 1449 (Modified)

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

			Halloran, et al., ARTHRITIS RHEUM 39:810-819, 1996
			Schimmer, et al., J. IMMUNOL 160: 1455-1477, 1998.
			Oppenheimer-Marks, et al., J. CLIN INVEST 101: 1261-1272, 1998.
			Wegner, et al., SCIENCE 247:456-459, 1990.
			Bloemen, et al., AM J. RESPIR CRIT CARE MED 153:521-529, 1996.
			Wegner, et al., LUNG 170: 267-279, 1992.
			Mulligan, et al., J IMMUNOL 154:1350-1363, 1995.
			Nagase, et al., AM J RESPIR CRIT CARE MED 154:504-510, 1996.
			Bennet, et al., J PHARMACOL EXP THER, 280:988-1000, 1997
			Hasagawa, et al., INT IMMUNOL, 6:831-838, 1994.
			Herrold, et al., CELL IMMUNOL, 157:489-500, 1994.
			Tanaka, et al., J. IMMUNOL, 151:5088-5095, 1993.
			Kawasaki, et al., J. IMMUNOL, 150:1074-1083, 1993.
			Panes, et al., GASTROENTEROLOGY, 108:1761-1769, 1995.
			Hallahan, et al., PROC NATL ACAD SCI USA, 94:6432-6437, 1997.
			Tamiya, et al., IMMUNOPHARMACOLOGY, 29(1):53-63, 1995.
			Hartman, et al., CARDIOVASC RES, 30(1): 47-54, 1995.
			DeMeester, et al., TRANSPLANTATION, 62(10): 1477-1485, 1996.
			Horgan, et al., AM J PHYSIOL, 261(5):H1578-H1584, 1991.
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			Cosimi, et al., J. IMMUNOL, 144: 4606-4612, 1990.
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			He, et al., OPTHALMOL VIS SCI, 35: 3218-3225, 1994.
			Zeng, et al., TRANSPLANTATION, 58: 681-689, 1994.
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			Aoudjit, et al., J. IMMUNOL, 161: 2333-2338, 1998.
			Gross, et al., SCIENCE 281, 703-706, 1998.

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DATE: April 18, 2000 SHEET _1_ of _2

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		Von Adrian, V., Chambers, J.D., McEnvoy, L.M. Bargatze, R.F., Arfos, K.E., Butcher, E.C., 1991, Two-Step Model of Leukocyte-Endothelial Cell Interactions in Inflammation, Proc. National Acad. Sci. USA, 88:7538-7542. 6
		Ley, K., Gaehtgens, P., Fennie, C., Singer, M.S., Lasky, L.H., Rosen, S.D., 1991, Lectin-Like Cell Adhesion Molecule 1 Mediates Rolling in Mesenteric Venules, in vivo, BLOOD, 77:2553-2555. 7
ARTICLE NOT PROVIDED		Higuchi, T., Stella, V., Pro-drugs as Novel Delivery Systems, Vol. 14 of the A.C.S. SYMPOSIUM SERIES. 8
		Roche, E.B., Bioreversible Carriers in Drug Design, AMERICAN PHARMACEUTICAL ASSOCIATION AND PERGAMON PRESS, 1987. 9
		Prescott, E., Methods in Cell Biology, Volume XIV, Academic Press, New York, NY (1976), p. 33 et seq. 10
		Berge, S.M., et al., J. PHARMACEUTICAL SCIENCES, 1977, 66:1 et seq. 11
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			Oppenheimer-Marks, et al., J. CLIN INVEST 101: 1261-1272, 1998.	16
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			Bennet, et al., J PHARMACOL EXP THER, 280:988-1000, 1997	22
			Hasagawa, et al., INT IMMUNOL, 6:831-838, 1994.	23
			Herrold, et al., CELL IMMUNOL, 157:489-500, 1994.	24
			Tanaka, et al., J. IMMUNOL, 151:5088-5095, 1993.	25
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			Panes, et al., GASTROENTEROLOGY, 108:1761-1769, 1995.	27
			Hallahan, et al., PROC NATL ACAD SCI USA, 94:6432-6437, 1997.	28
			Tamiya, et al., IMMUNOPHARMACOLOGY, 29(1):53-63, 1995.	29
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			DeMeester, et al., TRANSPLANTATION, 62(10): 1477-1485, 1996.	31
			Horgan, et al., AM J PHYSIOL, 261(5):H1578-H1584, 1991.	32
			Nakanishai, et al., EXP NEUROL, 121:215-219, 1993.	33
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			Cosimi, et al., J. IMMUNOL, 144: 4606-4612, 1990.	39
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			He, et al., OPTHALMOL VIS SCI, 35: 3218-3225, 1994.	42
			Zeng, et al., TRANSPLANTATION, 58: 681-689, 1994.	43
			Harning, et al., TRANSPLANTATION, 52: 842-845, 1991.	44
			Aoudjit, et al., J. IMMUNOL, 161: 2333-2338, 1998.	45
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